

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1, 3-11, 14-16, and 20-27 are now pending in this application.

Interview Summary

Applicant wishes to thank the Examiner for discussing the present application during the interview of September 12, 2008. In accordance with the request in the Interview Summary that the Applicant file a statement of substance of interview, please be advised that the Interview Summary accurately summarizes the interview except that Applicant respectfully submits that the box stating that an agreement with respect to the claims was reached, as noted in the comments of the Interview Summary regarding the substance of the interview.

Rejections under 35 U.S.C. § 112

Claims 1, 3-8, 10, 14, and 20-27 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, and under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicant respectfully submits that the amendments to the claims render these rejections moot, as noted in the Interview Summary. Reconsideration and withdrawal of these rejections is respectfully requested.

Rejection under 35 U.S.C. § 102

Claims 1, 3-8, 10, 14, and 20-27 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. 4,894,052 to Crawford (hereafter “Crawford”). This rejection is respectfully traversed.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See generally M.P.E.P. § 2131.

Crawford discloses an introducer 10 with a needle 11 and a catheter 14. See col. 4, lines 43-50 of Crawford. The catheter 14, which is fitted within the introducer 10, is made of a translucent or transparent material and the needle 11 is fitted within an interior of the catheter 14. See col. 4, lines 47-50, and Figures 2 and 4 of Crawford. The needle 11 has a hole in its tip 12, permitting blood to flow into the bore 22 of the needle 11. See col. 5, lines 3-13, and Figures 2 and 4 of Crawford. The needle 11 also includes an access port 21 that permits blood to flow from the bore 22 of the needle 11 into an annular cavity 17 which is formed by the catheter 14 and surrounds the needle 11. See col. 5, lines 13-22, and Figures 2 and 4 of Crawford. The introducer 10 further includes a guide wire 24 which can be advanced within the needle 11 to close the access port 21 and prevent blood flow through the access port 21 and into the annular cavity 17. See col. 6, line 61, to col. 7, line 17, and Figure 4 of Crawford.

However, Crawford does not disclose an indicator system comprising, among other things, an insertion tube with an inlet opening formed on an outer surface of the insertion tube, an opening at an extreme end of a distal end portion of the insertion tube, and a fluid communication pathway of the insertion tube that is formed between the insertion tube and an elongated member, as recited in independent claims 1, 10, 14, 20, 21, and 22. Claims 3-8 and 23-27 depend from claim 1.

Crawford does not disclose an insertion tube with both an inlet opening formed on an outer surface of the insertion tube and an opening at an extreme end of a distal end portion of

the insertion tube. The catheter 14 of Crawford only includes a single opening at its distal end and does not also include an inlet opening formed on an outer surface of the catheter.

In regard to the needle 11, 11a of Crawford, the Office identifies the needle as an insertion tube and the guide wire 24 as an elongated member on pages 2 and 3 of the Office Action. The needle 11 of Crawford does not include the recited fluid communication pathway that is formed between the insertion tube and an elongated member because Crawford teaches that the guide wire 24 closes the access port 21, thus blocking flow of blood within the bore 22 of the needle 11. It appears that the outer diameter of the guide wire 24 is equivalent to the inner diameter of the bore 22 of the needle 11 so that the guide wire 24 may block the flow of blood within the bore 22. Blood is not a fluid with low viscosity. Given the small dimensions of Crawford's bore 22 and guide wire 24, it is virtually impossible that Crawford's device would provide a reliable blood indication, whether or not there is a perfect match between the outer diameter of the guide wire 24 and the inner diameter of the bore 22 of the needle 11. Therefore, the needle of Crawford cannot include a fluid communication pathway that is formed between the needle 11 and the guide wire 24 because the guide wire 24 of Crawford is constructed to block blood flow within the needle 11.

Crawford does not anticipate claims 1, 3-8, 10, 14, and 20-23 because Crawford does not disclose all of the features of these claims. Reconsideration and withdrawal of this rejection is respectfully requested.

Allowable Subject Matter

Applicant gratefully acknowledges the allowance of claims 9, 11, 15, and 16.

Conclusion

Applicant submits that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 11/10/2008

By Kevin McHenry

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 295-4011
Facsimile: (202) 672-5399

Glenn Law
Attorney for Applicant
Registration No. 34,371

Kevin McHenry
Attorney for Applicant
Registration No. 62,582